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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/764,861 | 01/26/2004 | Paul T. Jacobs | JJM-408 CON1 | 9404 |
| 27777 | 7590 | 07/26/2006 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | MCKANE, ELIZABETH L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1744 | |

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/764,861 | JACOBS ET AL. | |
| | Examiner Leigh McKane | Art Unit 1744 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 May 2006.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-20 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 26 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 012604.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7, 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forstrom et al. (U.S. Patent No. 4,169,124) in view of Cummings et al. (U.S. Patent No. 4,744,951).

As to claims 1-7, 9, and 10, Forstrom et al. discloses a method of hydrogen peroxide sterilization wherein a small amount of dilute hydrogen peroxide **12** is introduced into a chamber **1**, along with an article **9,10** to be sterilized, and the hydrogen peroxide then vaporized to sterilize the article. Vaporization occurs when the chamber is evacuated through diffusion restriction **5**. See col.4, lines 4-25; Figure 1 and 2. Forstrom et al. does not teach selectively drawing water vapor from the chamber to increase a ratio of hydrogen peroxide to water in the chamber.

Cummings et al. teaches a method of sterilizing wherein an article is placed into a sterilizing chamber **22**, the chamber is evacuated (dried), a dilute (0.05-5%) aqueous solution of H_2O_2 is introduced into an enclosure **10** having a diffusion restriction **20** in fluid communication with the chamber **22** and vaporized. Thereafter, water vapor is drawn off through port **14** to increase the ratio of H_2O_2 to water and the H_2O_2 is subsequently furnished to the article within evacuated chamber **22** for sterilization. See Figure and col.3, lines 29-55. Cummings et al.

discloses that "conditions within the chamber" are controlled to cause the preferential vaporization of water from the solution. As shown in the Examples, the pressure and temperature are controlled to achieve this preferential vaporization. Cummings et al. discloses a preferred final concentration of hydrogen peroxide (50-80%), which encompasses the claimed ratios.

It would have been obvious to one of ordinary skill in the art to preferentially remove the water vapor from the generated vapor of Forstrom et al. since Cummings et al. teaches that doing so yields a higher peroxide concentration and thus, an improved sterilization efficacy. See Examples 3-5.

With respect to claims 11-19, it is known to those in the art that vaporization of a component of a solution occurs when the vapor pressure of the component exceeds that of its surroundings. This vaporization can be achieved by increasing the vapor pressure of the component through two means: heating the solution to increase the vapor pressure thereof or lowering the surrounding pressure. (See for example Forstrom et al. which teaches imposing a vacuum on the chamber in combination with heat to promote vaporization of the solution.) Thus, it would have been obvious to control both of these parameters in any desired combination or order in order to control vaporization of the water from the solution and to achieve the desired final concentration of hydrogen peroxide, as taught by Cummings et al..

3. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forstrom et al. in view of Cummings et al. as applied to claim 18 above, and further in view of Spencer et al. (U.S. Patent No. 5,656,238).

Forstrom et al. discloses imposing a vacuum on the chamber in order to dry the chamber but does not teach applying energy thereto. Spencer et al. teaches that the application of a plasma during an initial evacuation step promotes drying of the chamber and allows a desired pressure to be attained more quickly than without the plasma. See Abstract. For these reasons, it would have been obvious to apply energy during the drying step of the combination *supra*.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 1-20 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of prior U.S. Patent No. 6,656,426 (cited on the IDS of 26 January 2004). This is a double patenting rejection.

Information Disclosure Statement

6. The German document on the information disclosure statement filed 26 January 2004 has been considered in view of the Abstract filed 2 May 2006.

Terminal Disclaimer

7. The terminal disclaimers filed on 2 May 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,325,972 and 6,627,150 have been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (5:30 am-3:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leigh McKane
Leigh McKane
Primary Examiner
Art Unit 1744

elm
12 July 2006